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REMARKS

I. Claim Rejections – 35 U.S.C. §103(a)

A. US 6,245,351 to Nara et al. ("Nara")

Claims 1, 3, 6-18, 20 and 25-28 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over US 6,245,351 to Nara et al. ("Nara").

For the following reasons, Applicants submit that the structure, release profile and dissolution rate of the claimed pharmaceutical dosage form are different from and not suggested by the controlled-release composition disclosed by Nara.

As broadly defined by claim 1 of Nara, the prior art composition comprises a pharmaceutical core layered with a coating comprising (i) a water-insoluble ethyl cellulose and (ii) a swellable, cross-linked polymer. Because the coating composition contains a swellable polymer, Nara states that the release of the active ingredient is increased over time during drug passage through the upper to lower small intestines and large intestines as the swellable polymer swells increasingly after administration (col. 7, lines 25-32). The coating composition may also contain a hydrophilic substance (col. 4, lines 60-63).

Examples 1 and 9 of Nara disclose pharmaceutical compositions layered with a three (3) component coating composition: (i) a water-insoluble ethyl cellulose (ethyl cellulose); (ii) a swellable, cross-linked polymer (a crosslinked polyacrylic polymer) and (iii) a hydrophilic substance (hydroxypropylmethylcellulose). The coated compositions of Examples 1 and 9 provide the basis for the data shown in Figures 1 and 2, respectively, of Nara. In this regard, the Examiner's attention is directed to Experimental Examples 1 and 2 at column 13.

Specifically, Figure 1 shows the dissolution rate of the composition of Example 1 at

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pH1.2 and pH6.8. Figure 2 shows the release rate of the composition of Example 2 at pH1.2 and pH6.8. When these two figures are considered in view of the specification, the following conclusions regarding the compositions disclosed by Nara become apparent:

- 100% of the active ingredient is released at pH 6.8 in about 6 hours following administration (Figure 2), and
- 40% of the active ingredient is dissolved at pH 6.8 in about 6 hours following administration (Figure 1).

As disclosed and claimed, the core of the claimed dosage form comprises an omeprazole compound as the active ingredient, an alkaline additive and a swelling agent. The core is layered with a semipermeable membrane. The ingredients of the semipermeable membrane include a water-insoluble polymer and a modifying agent. The semipermeable membrane is defined in claim 1 by the transition expression "consisting essentially of". Therefore, by the transition expression "consisting essentially of", the semipermeable membrane of the claimed invention does not include unrecited ingredients that would affect the properties of the semipermeable membrane. The dosage form is not enteric coated.

The structure or formulation of the claimed dosage form is different from and not suggested by Nara. First, in accordance with the claimed invention, the swellable agent or polymer is found in the pharmaceutical core. In contrast, the swellable agent or polymer is in the coating composition disclosed by Nara. Second, by the transition expression "consisting essentially of", the semipermeable membrane of the claimed invention does not include unrecited ingredients that would affect the properties of the semipermeable membrane. In contrast, the coating composition disclosed by Nara contains a hydrophilic substance and the

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swellable agent , both of which are excluded from the semipermeable membrane of the claimed invention.

As a result of the differences in structure and formulation, the claimed dosage form possesses a different release profile and dissolution rate when compared to the compositions disclosed by Nara. The targeted release site of the claimed dosage form is the small intestine where omeprazole is released, absorbed and distributed in the body (See specification at page 4, lines 21-22). In contrast, Figure 2 of Nara suggests a release profile where the targeted release site of the active ingredient is the large intestine, i.e., 5-6 hours after administration.

For all of the foregoing reasons, therefore, Applicants respectfully submit that the structure, formulation, release profile and distribution rate of the claimed invention are not suggested by Nara. Withdrawal of the §103 rejection based on Nara is requested.

B. Nara in view of WO 98/54711

Claims 4, 5 and 23-26 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Nara in view WO 98/54711 in the name of Cotton et al. ("Cotton").

As stated by the Examiner on page 4 of the Office Action, Cotton is cited for the disclosure of the magnesium salt of omeprazole as an active ingredient.
Applicants submit that Cotton does not over come the deficiencies of Nara to suggest the claimed invention for the reasons given in the preceding Section. Withdrawal of the §103 rejection based on Nara in view of Cotton is requested.

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It is submitted the following documents made or record but not relied upon neither disclose not suggest the claimed invention: US 4,840,799 to Appelgren et al.; US 5,246,714 to Dahlinder et al.; US 6,110,498 to Rudnic et al.; US 6,132,770 to Lundberg; and US 6,210,712 to Edgren et al.

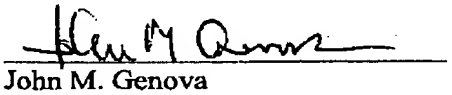
CONCLUSION

Applicants have made a good faith attempt to respond to the Office Action. It is respectfully submitted that claims 1, 3-18, 20 and 23-28 are in condition for allowance, which action is earnestly solicited.

Any fees due in connection with this response should be charged to Deposit Account No. 23-1703.

Dated: 18 October 2004

Respectfully submitted,



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